



K963964

510(k) Summary

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(a) (1) **Submitter's name, address**
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(2) **Device trade or proprietary name:** AVL COMPACT 3 pH/Blood Gas Analyzer

Device common or usual name or classification name
 pH / Blood Gas Analyzer

Product Nomenclature	Classification Number	Class	Panel
BLOOD GASES / PH	75 CHL	II	CHEMISTRY

(3) **Substantial Equivalence**

Under 510(k) notification number K942616, AVL currently markets the AVL COMPACT 2 pH/Blood Gas Analyzer.

Additionally, as in the former 510(k) submission, the AVL COMPACT 3 is substantially equivalent to the AVL Model 995 pH / Blood Gas Analyzer [K895317] and AVL COMPACT 2 pH / Blood Gas Analyzer [K942616].

(4) **Description of the new device**

We do not consider the AVL COMPACT 3 a new device, but a re-engineering of our existing, COMPACT 2 to increase its utility in the hands of our customers. The most externally apparent modification enhances the current display and simplified YES, NO keypad with a full 10-key numeric keypad for the easy input of patient identification and other such numeric data.

The AVL COMPACT 3 pH / Blood Gas Analyzer is a fully automatic, microprocessor-controlled medical instrument that measures pH, PCO_2 and PO_2 . Communication to the device is accomplished simply with the use of a keypad. The analyzer communicates to the user through a 4-line alphanumeric display with 20 characters per line and with a thermal printer using heat sensitive paper to output measured values, calibration reports, electrode voltages and other information.

Calibration is performed automatically by the instrument on power-on. One-point calibration of PCO_2 and PO_2 occurs continually during operation and following each sample analysis. One-point calibration of pH is performed automatically either at 1, 2 or 3 hour intervals determined by the instrument based on calibration drift, or selected to be performed automatically at 30 minute or 1 hour, fixed intervals by the user. A complete, 2 point calibration of all sensors may be selected to occur automatically at 8 or 12 hour intervals by the user. All calibrations may be initiated by the user as desired.

Automatic cleaning is performed by the instrument on initial power-on and prior to each 2-point full calibration. The device contains additional diagnostic programs features to enable the user to easily customize some features of operation, or to troubleshoot the cause of any operational errors.

Quality control processing is provided for up to 34 samples of each of 3 levels of control material and to calculate mean, standard deviation and coefficient of variation on these samples to aide the user in performance and documentation of quality control for this instrument.

(5) Intended use of the device.

The AVL COMPACT 3 pH / Blood Gas Analyzer is intended to be used for the measurement of pH, PCO_2 and PO_2 in samples of whole blood.

(6) Technological characteristics of the device

The COMPACT 3 utilizes conventional technology for measurement (galvenometric for pH and PCO_2 , polarographic for PO_2) with microprocessor controlled, fully automatic calibration and measurement.

Technical Specifications

Measured Values	Displayed Range	Resolution of Display	Units
pH	6.0 - 8.0	0.001	
PCO_2	4 - 200	0.01	mmHg
PO_2	0 - 742	0.01	mmHg
barometric pressure	300 - 800	0.1	mmHg
	375 - 1058	1	mBar

Within Run Precision Whole Blood Measurement	Measurement Range	SD	Units
pH	6.0 - 8.0	≤ 0.005	
PCO_2	0 - 40	≤ 0.8	mmHg
	40-200	≤ 3.0	mmHg
PO_2	0 - 143	≤ 1.2	mmHg
	143 - 742	≤ 15.0	mmHg

Input Values		Range (conv.)*	Default	Units
Patient temperature	T	14 - 44	37	°C
Total hemoglobin	tHb	1 - 26	15	g/dL
Hemoglobin type		adult / fetal	adult	--
	P_{50} adult	15 - 40	26.7	mmHg
	P_{50} fetal	15- 40	21.5	mmHg
Fraction of Inspired Oxygen	FIO_2	0.11 - 0.99	0.21	mmHg
Respiratory Quotient	RQ	0.71 - 1.99	0.84	--
Patient age		0 - 99	--	years
Patient sex		male / female	--	--

* SI units are also available

Data Management

Printout	built-in thermal printer
Interface	2 x RS 232, 9-pin SUBMIN D / F 1 x RS 232, 25-pin SUBMIN D / F

Gas Supply

Calibration Gas 1	20% O ₂ , 5.5% CO ₂ , bal N ₂	(± 0.03% absolute)
Calibration Gas 2	10% CO ₂ , bal N ₂	(± 0.03% absolute)
Input pressure	3 - 4 bar (43.5 - 58 psi)	

Sample Data

Sample type	blood (serum or plasma for pH only)
Sample input via	syringe, capillary, Microsampler
Sample volume	≥ 90 µL syringe mode ≥ 55 µL capillary mode 60 µL Mini sample with capillary 25 - 55 µL Micro sample with capillary
Reported units	conventional, SI
Sample rate	≤ 32 samples/hour with interruption of conditioning ≤ 28 samples/hour without interruption of conditioning

Temperature / Humidity

Ambient temperature	15 °C - 32 °C, (59 °F - 89.6 °F)
Measuring chamber temperature	37 °C ± 0.1 °C, 98.6 °F ± 0.18 °F
Relative humidity	20 - 90% (non-condensing)

Electrical Supply

Voltage range	100 - 240 V AC, self adapting
Frequency	50 - 60 Hz
Power consumption (max.)	typical 65 VA max. 110 VA, depending on actual operating mode

Dimensions / Weight

Width	34 cm	(13.4 inch)
Depth	31.5 cm	(12.4 inch)
Height	34 cm	(13.4 inch)
Weight	13 kg	(28.7 pounds)

Classification

Safety category	I
Instrument type	B (following ÖVE - MG/EN 60 601-1, IEC 601-1)
Operation type	for continuous operation
Protective system	IP20
EX protection	The device is not specified for operation inside explosion-hazardous areas.

(b) (1) Summary of nonclinical tests submitted with the premarket notification for the device.

The scope of nonclinical tests for the COMPACT 3 is limited only to the differences between the COMPACT 3 and the preexisting COMPACT 2 pH / Blood Gas Analyzer [K942616]. Below are listed summarized descriptions of the validation performed for these changes.

Numeric Keypad

Operation of the numeric keypad was validated by test of input values from the upper and lower limits in addition to typical input values. The numeric keypad function test was judged passed.

Optimization of Sample Volume Requirements

With the addition of the "Mini" sample mode, the COMPACT 3 provides the user with four modes of sample measurement: Syringe, Capillary, Mini and Micro sample modes.

The measurement in each of these sampling modes was optimized independently, then validated through the measurement of whole blood samples which have been tonometered to gravimetrically prepared gas mixtures in each of these 4 sample modes. The means of five measurements in each mode taken at 10 levels of CO₂ and O₂ gas mixtures spanning the reportable range of the COMPACT were compared using standard statistical methods¹ to determine that no significant difference ($P < 0.05$) exists between measurement results in each of these 4 modes.

mode	mean	bias	slope	y-intercept	s(y*x)	correlation coefficient
pH vs OMNI range: 7.00 to 7.48						
syringe	7.263	-0.016	1.0334	-0.262	0.0066	0.99945
capillary	7.247	-0.016	1.0321	-0.248	0.0078	0.99923
mini	7.254	-0.010	1.0209	-0.162	0.0062	0.99950
micro	7.254	-0.010	1.0078	-0.065	0.0085	0.99904
PCO₂ vs Tonometry range: 21 to 140 mmHg						
syringe	55.6	+0.43	0.9963	+0.631	0.5696	0.99991
capillary	55.7	+0.56	1.0025	+0.439	0.4089	0.99995
mini	55.4	+0.26	0.9861	+1.012	0.9013	0.99977
micro	55.91	+0.77	1.0120	+0.104	0.5499	0.99992
PO₂ vs Tonometry range: 0 to 660 mmHg						
syringe	213.4	-4.48	0.9708	+2.077	2.3981	0.99995
capillary	215.1	-2.82	0.9781	+1.925	2.2952	0.99995
mini	214.7	-3.89	0.9725	+2.575	2.6803	0.99993
micro	215.0	-2.88	0.9759	+2.351	3.3438	0.99990

table 1: summary of comparisons between measurement modes COMPACT 3

¹ Bland JM, Altman DG. Statistical Methods for Assessing Agreement Between Two Methods of Clinical Measurement. The Lancet, Feb 8, 1986, 307-10.

Additionally, the mean pH value in each mode was compared to the pH measurement obtained on the same from an AVL OMNI pH/Blood Gas Analyzer at pH values resulting from tonometry at each of 7 of the CO₂ gas concentrations used and found to have no significant difference ($P < 0.05$).

Adoption of NCCLS Recommendations for Calculated Values

The equations used for all calculated values on the Compact 3 are listed in the Appendix of the Operators Manual included with this submission and have been verified by input of values representing the range and typical values for each parameter.

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

Because of the limited scope of changes between COMPACT 3 and the preexisting COMPACT 2 pH / Blood Gas Analyzer [K942616], no clinical tests are submitted with the premarket notification for the device.

(b) (3) Conclusions drawn from the clinical and nonclinical trials.

There is no significant difference in the measurement values obtained in analysis of whole blood between any of the sampling modes available on the COMPACT 3 pH/Blood Gas Analyzer.